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India

FAIRS Product Specific

Proposed Amendment to the PFA Rule to the Labeling of Pre-packaged Food

2008

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Report Highlights:

On May 15, 2008, the Department of Health, Ministry of Health and Family Welfare, Government of India (GOI) issued a draft Gazette notification under the Prevention of Food Adulteration Act (PFA), proposing an amendment to the labeling requirements for pre-packaged foods. Additionally, on May 16, 2008 the Ministry released a final notification to further delay full implementation of the notification related to the labeling of pre-packaged food rule (the Prevention of Food Adulteration (7th Amendment) Rules, 2006) from May 20, 2008 to October 20, 2008.

Includes PSD Changes: No
Includes Trade Matrix: No
Trade Report
New Delhi [IN1]
[IN]

The Ministry of Health and Family Welfare issued a draft Gazette notification on May 15, 2008 proposing amendments to the labeling requirements for prepackaged foods (the Prevention of Food Adulteration (7th Amendment) Rules, 2006). The new proposed rules will be termed as Food Adulteration (Second Amendment) Rules, 2008.

The Ministry through another notification on May 16, 2008, delayed the complete implementation of the earlier labeling of pre-packaged food rule 2006 from May 20, 2008 to October 20, 2008.

Post reported on earlier notifications on labeling requirements for pre-packaged foods via IN5134, IN6085, IN7076 and IN8040.

Disclaimer: This summary is based on a cursory review of the subject announcement and therefore should not, under any circumstances, be viewed as a definitive reading of the regulation in question, or of its implications for U.S. agricultural exports to India.

Details on the draft Gazette notification no. G.S.R. 380(E) dated May 15, 2008 'Prevention of Food Adulteration (Second Amendment) Rules, 2008'.

Type of Regulation:	Draft
Publication Date:	May 15, 2008
Notification to the WTO:	Not Notified (as of May 23, 2008)
Effective Date:	Date of publication of the final notification in the Official Gazette of India
Products Affected:	All prepackaged foods
Agency In charge:	Department of Health, Ministry of Health and Family Welfare, Government of India
Time period for receiving Comments/Suggestions:	Sixty days after publication date of the draft notification
Comments/suggestions should be addressed to:	Secretary Ministry of Health and Family Welfare Government of India Nirman Bhawan New Delhi – 110 011

Note: The text of the notification can be assessed at: <http://www.mohfw.nic.in/Noti%20380.pdf> . Additionally, a scanned copy of the notification is attached along with this report.

Details on the final Gazette notification (corrigendum) no. GSR 383(E), dated May 16, 2008

Type of Regulation:	Final
Publication Date:	May 16, 2008

Notification to the WTO:	Not Notified (as of May 23, 2008)
Effective Date:	May 16, 2008
Products Affected:	All prepackaged foods
Agency In charge:	Department of Health, Ministry of Health and Family Welfare, Government of India

The text details of the notification can be assessed at:

<http://www.mohfw.nic.in/Noti%20383.pdf>

Major Changes:

The notification 'Prevention of Food Adulteration (Second Amendment) Rules; 2008' (**no. G.S.R. 380(E) dated May 15, 2008**), proposes amendments to the labeling requirements for prepackaged food and contains some revisions / changes over those covered by the notification on the labeling of prepackaged food rule (number 491 (E), dated August 21, 2006, Text of the notification is available at: <http://www.mohfw.nic.in/Noti%20491.pdf>). Some of the main focus areas of the proposed amendment to the PFA rules 'Prevention of Food Adulteration (Second Amendment) Rules; 2008' are given below:

- List of Ingredients, nutritional information or nutritional facts and information on health claims
- Raw agriculture commodities, non-nutritive products, alcoholic beverages, single ingredient products, foods shipped in bulk (detailed categories specified on page 14 of the notification) are exempted from declaration on nutritional information
- Labeling requirements of irradiated foods
- Labeling requirements for proprietary foods
- Information on colors and flavors
- Declaration of net content by weight or volume or number
- Exemptions from labeling requirements
- Special labeling requirements for allergenic and / or hypersensitive ingredients, withdrawn
- Information on added flavors

For more information, visit the Ministry of Health website at: www.mohfw.nic.in/pfa.htm

Background and Post comments:

On August 21, 2006 the MOHFW had issued a final Gazette notification (**no. G.S.R. 491(E) dated August 21, 2006**) on labeling requirements for prepackaged foods (the Prevention of Food Adulteration (7th Amendment) Rules, 2006).

The regulation was given a one-year implementation period except for rule number 9 (pertaining to the sale of insect-damaged dry fruits and nuts), which came into force on November 20, 2006. The MOHFW delayed the implementation of the rules with the latest implementation date due on May 20, 2008, except rule number 8 (regarding the insertion of the guideline 'Product not to contain any substances which may be injurious to health' – Tobacco and Nicotine should not be used as ingredients in any food products), which was implemented on August 20, 2007.

The Ministry received comments and concerns regarding the difficulty in conforming to the complete implementation of the Gazette notification **(no. G.S.R. 491(E) dated August 21, 2006)** on labeling requirements for prepackaged foods (the Prevention of Food Adulteration (7th Amendment) Rules, 2006). The Ministry has now delayed the implementation of the rules until comments are considered.

Finally, on May 15, 2008, the Ministry released a draft Gazette notification **(no. G.S.R. 380(E))** proposing amendments to the labeling requirements for prepackaged foods (the Prevention of Food Adulteration (7th Amendment) Rules, 2006). Subsequently, the Ministry released another notification (corrigendum no. **GSR 383(E), dated May 16, 2008**) delaying the complete implementation of the labeling of the pre-packaged food rule **(no. G.S.R. 491(E) dated August 21, 2006)** from May 20, 2008 to October 20, 2008.

The chronology of events related to the release of notifications by the Ministry of Health and Family Welfare (MOH&FW) on the labeling requirements for pre-packaged foods is given below.

	MOH&FW Notification	Web-link to assess notification text	Date of release	GAIN Report No.
1.	No. G.S.R. 694(E),	http://www.mohfw.nic.in/694.pdf	November 25, 2005	IN5134
2.	No. G.S.R. 491 (E), the Prevention of Food Adulteration (7 th Amendment) Rules, 2006	http://www.mohfw.nic.in/Noti%20491.pdf	August 21, 2006	IN6085
3.	No. G.S.R. 518 (E),	http://www.mohfw.nic.in/Noti%20Corrig%20518%20%20.pdf	July 31, 2007	IN7076
4.	No. G.S.R. 70 (E)	http://www.mohfw.nic.in/Corrigendum%20GSR%2070%20-%20E.pdf	February 5, 2008	IN8040
5.	No. G.S.R. 380 (E)	http://www.mohfw.nic.in/Noti%20380.pdf	May 15, 2008	IN8057
6.	GSR 383(E)	http://www.mohfw.nic.in/Noti%20383.pdf	May 16, 2008	IN8057

The websites are mentioned for readers' convenience; USDA does NOT in any way endorse, guarantee the accuracy of, or necessarily concur with the information contained in the above sites.

[भाग II—खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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टिप्पणी :—मूल नियम भारत के राजपत्र में अधिसूचना संख्यांक का०नि०आ० 2106, तारीख 12 सितंबर, 1955 द्वारा प्रकाशित किए गए थे और सो०का०नि० 208(अ), तारीख 25 मार्च, 2008 द्वारा उनमें अंतिम संशोधन किए गए थे।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 15th May, 2008

G.S.R. 380(E).—The following draft of certain rules further to amend the Prevention of Food Adulteration Rules, 1955, which the Central Government proposes to make in exercise of the powers conferred by section 23 of the Prevention of Food Adulteration Act, 1954 (37 of 1954), in circumstances which in the opinion of the Central Government render it necessary and in the public interest, to make rules without consultation with the Central Committee for Food Standards, is hereby published, as required by sub-section (1) of the said section for the information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will be taken into consideration after sixty days of its publication in the Gazette of India. Any objections or suggestions received from any person with respect to the said draft rules on or before the date so specified shall be considered by the Central Government;

Objections or suggestions, if any, may be addressed to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi - 110 011;

DRAFT RULES

1. (1) These rules may be called the Prevention of Food Adulteration (Second Amendment) Rules, 2008.
- (2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Prevention of Food Adulteration Rules, 1955 (hereinafter referred to as the said rules), - in rule 2,
 - (i) clauses (j), (k), (l) and (m) shall be omitted;

(ii) for clause (o), the following clause shall be substituted, namely:-

“(o) “foods for special dietary uses” means foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.”;

(iii) clause (q), clause (r), clause(s), clause(t) and clause(u) shall be omitted.

3. In rule 32 of the said rules,-

(1) in clause (b),-

(i) for paragraph (2) relating to List of Ingredients, the following paragraph shall be substituted, namely:-

“(2) List of Ingredients: Except for single ingredient foods, a list of ingredients shall be declared on the label in the following manner: -

- (i) the list of ingredients shall contain an appropriate title, such as the term “ingredients”;
- (ii) the names of ingredients used in the product shall be listed in descending order of ingoing weight at the time of manufacture of the food;
- (iii) where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, and shall be accompanied by a list, in brackets, of its ingredients in descending order of weight;

Provided that where a compound ingredient for which a name has been established in these rules constitutes less than five percent of the food, the ingredients other than food additives which serve a technological function in the finished product need not to be declared;

- (iv) added water shall be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients;

Provided that water or other volatile ingredients evaporated in the course of manufacture need not to be declared;

Provided further that in the case of dehydrated or condensed food, which are intended to be reconstituted by the addition of water only, the ingredients may be listed in order of weight in the reconstituted product and shall contain a statement such as “ingredients of the product when prepared in accordance with the directions on the label.”

- (v) every package of food sold as a mixture or combination shall disclose the ingoing percentage, by weight or volume, as the case may be, of an ingredient at the time of the manufacture of the food (including compound ingredients or categories of ingredients) that-

[अध्याय 1—लेबलिंग 3(i)]

भारत का रक्षणधर्म : अस्वास्थ्य

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- (A) is emphasised as present on the label through words or pictures or graphics; or
- (B) is not within the name of the food but, is essential to characterise the food and is expected to be present in the food by consumers if the omission of the quantitative ingredient declaration will mislead or deceive the consumer;

Provided that the above disclosure is not required where ingredient has been used as flavouring agents in accordance with the provisions of rule 63 or herbs, spices and condiments used for the purposes of flavouring;

Provided further that the above disclosure is not required where the drained net weight is indicated on the label as required or in case of such food products where specific provisions are stipulated under these rules or where an pictorial representation of a serving suggestion is made for consumer information and use;

- (vi) the nutritional information or nutritional facts per 100 gm or 100ml or per serving of the product shall be given on the label containing the following: -

- (A) energy value expressed in kcal;
- (B) the amounts of protein, carbohydrate (specify quantity of sugar) and fat expressed in gram (g);
- (C) the amount of any other nutrient for which a nutrition or health claim is made;

Provided that where a claim is made regarding the amount or type of fatty acids or the amount of cholesterol, the amount of saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids and cholesterol shall be declared, and the amount of trans fatty acid shall be declared in addition to the other requirements stipulated above;

- (D) wherever, numerical information on vitamins and minerals is declared, it shall be expressed in metric units
- (E) where the nutrition declaration is made per serving, the amount in gram (g) or milliliter (ml) shall be included for reference beside the serving measure;
- (F) declaration of other nutrients, like, vitamins and minerals including sodium, potassium, dietary fibers shall be required in case any nutrition or health benefit claims are made upon the label or otherwise in respect of the food contained in the package;
- (G) in case a claim is made on the label with regard to the presence of mono or poly unsaturated fatty acids or presence of omega 3 or oryzanol which are considered good for health, the amount and type of fatty acids shall be declared on the label;

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Provided that-

(a) *the nutritional information may not be necessary, in case of foods such as raw agricultural commodities, like wheat, rice, cereals, spices, spice mixes, herbs, condiments, table salt, sugar, jaggery, etc, or non-nutritive products, like, soluble tea, coffee, soluble coffee, coffee-chicory mixture, packaged drinking water, packaged mineral water, alcoholic beverages, whole or cut fruits and vegetables, processed and pre-packaged assorted vegetables, fruits, vegetables and products that comprise of single ingredient, pickles, papad, which are not known source of nutrient or where it does not contain any added nutrient foods served for immediate consumption such as served in hospitals, hotels or by food services vendors or halwais, foods shipped in bulk which is not for sale in that form to consumers,*

(b) the compliance to quantity of declared nutrients on the label shall be according to the established practices.

Explanation:- For the purpose of this provision, at the time of analysis, due consideration, based on shelf-life, storage, and inherent nature of the food shall be kept in view in case of quantity declared nutrients;

(c) where nutrition or health claims relating to these are made upon the label or in case of hydrogenated vegetable fats or bakery shortening or fat spreads, the amount of saturated fat and trans fat shall be declared on the label;

(d) the foods, in which hydrogenated vegetable fats or bakery shortening is used shall declare on the label that hydrogenated vegetable fats or bakery shortening used- contains trans fats;

(e) both fat content and the saturated fatty acid content are expressed in grams, immediately following the words, 'saturated' and 'trans fat'. 'reduced in trans fat' and 'lower in' trans fat;

Provided further that nutrient content claims in foods containing trans fat, 'free of trans fat' (less than 0.2 g trans fat per serving of the food) or claim for 'saturated fat free' or 'trans fat free' or any claim likely to have same meaning for the consumer, may be made only in case of food where the sum of saturated fat and trans fatty acids does not exceed 0.1 g of saturated fat per 100g or 100 ml.

Explanation.-

i For the purpose of this provision, at the time of analysis, due consideration, based on shelf-life, storage, and inherent nature of the food shall be kept in view in case of quantity of declared nutrients;

ii **"nutrition claim"** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals;

[भाग]—खण्ड 3(i)]

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(ii) "health claims" means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health and include nutrient function claims- which describes the physiological role of the nutrient in growth, development and normal functions of the body; other functional claims concerning specific beneficial effect of the consumption of foods or their constituents, in the context of the total diet on normal function or biological activities of the body and such claims relate to a positive contribution to health or to the improvement of function or to modifying or preserving health, or relate to the consumption of a food or food constituents, in the context of the total diet, to the reduced risk of developing a disease or health-related condition;

iv "risk reduction" in the context of health claims means significantly altering a major factor for a disease or health related conditions and diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect";

(ii) after the proviso relating to statement in capital letters for colours and flavours and before the NOTE given thereunder, the following shall be inserted, namely:-

"The common name or class name of the flavour shall also be mentioned on the statement regarding added flavours.";

(iii) for the last proviso, starting with words "provided also that declaration of flavours" and ending with the words "shall be declared on the label", the following shall be substituted, namely:-

"Provided that in case of artificial flavouring substances, the label shall declare the common names of the flavours, but in case of natural flavouring substances or nature identical flavouring substances, the class name of flavours shall be mentioned on the label and it shall comply with the label declaration as specified under rule 64 BB in case of added flavouring agents.".

(ii) for clause (d), the following clause shall be substituted, namely:-

"(d) (1) the net content by weight or volume or number as the case may be shall be declared on every package for all foods;

(2) in addition to the declaration of net contents, a food packed in a liquid medium shall carry a declaration of the drained weight of the food.

Explanation1. For the purposes of this requirement, liquid medium means water, aqueous solutions of sugar and salt, fruit and vegetable juices in canned fruits and vegetables only, or vinegar, either singly or in combination.

Explanation2. In declaring the net quantity of the commodity contained in the package, the weight of the wrappers and materials other than commodity shall be excluded.

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Provided that where a package contains a large number of small items of confectionery, each of which is separately wrapped and it is not reasonably practicable to exclude from the net weight of the commodity, the weight of such immediate wrappers of all the items of the confectionery contained in the package, the net weight declared on the package, containing such confectionery or on the label thereof may include the weight of such immediate wrapper if, and only if, the total weight of such immediate wrapper does not exceed :-

- (i) 8 per cent where such immediate wrapper is a waxed paper or other paper with wax or aluminium foil under strip; or
- (ii) 6 per cent in the case of any other paper, of the total net weight of all the items of confectionery contained in the package minus the weight of immediate wrapper.”;

(III) in clause (e), the following proviso shall be inserted, namely:-

“Provided that in case of packages containing bread and milk including sterilised milk, particulars under this clause shall not be required to be given on the label.”

(IV) for clause (h), the following clause shall be substituted, namely:-

“(h) **Irradiated foods.**— The label of a food, which has been treated with ionizing radiation, shall carry a written statement indicating the treatment in close proximity to the name of the food.”;

(V) for clause (I), the following clause shall be substituted, namely:-

“(I) **Exemptions from labelling requirements.**—

- (i) Where the total surface area of principal display panel of the package is not more than 100 square centimeter, the label of such package shall be exempted from the requirements of list of ingredients, Lot Number or Batch Number or Code Number, nutritional information and instructions for use, but these information shall be given on the wholesale packages or multipiece packages, as the case may be”.
- (ii) The requirement of mentioning the Best Before Date or Expiry Date may be exempted from declaration in packages with surface area of less than 10 square centimeter.
- (iii) in case of liquid products marketed in bottles which are reused for refilling, the particulars specified under clause (b) may not be required to be declared on such bottles.

(VI) after the last proviso and before Explanation –II, the following Explanation shall be inserted, namely:-

“**Explanation - I .-** “label” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package.”;

[MSP H - Table 3(i)]

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(VII) after Explanation-(III), the following Explanation shall be substituted, namely:-

Explanation - IV:- "Lot number" or "code number" or "batch number" means the number either in numerals or alphabets or in combination, representing the lot number or code number or batch number being preceded by the words "Lot No" or "Lot" or "code number" or "Code" or "Batch No" or "Batch" or any distinguishing prefix by which the food can be traced in manufacture and identified in distribution."

(VIII) after Explanation VI, the following Explanations shall be inserted, namely:-

Explanation - VII - "Prepackaged or Pre-packed food", means a food, which is placed in a package of any nature, in such a manner that the contents cannot be changed without tampering it and which is ready for sale to the consumer.

Explanation - VIII - "Best before" means the date which signifies the end of the period under any stated storage conditions during which the product shall remain fully marketable and shall retain any specific qualities for which tacit or express claims have been made and beyond that the date the food may still be perfectly satisfactory.

Explanation - VIII A - "Date of manufacture" means the date on which the food becomes the product as described;

Explanation VIII B - "Date of packaging" means the date on which the food is placed in the immediate container in which it will be ultimately sold.

Explanation VIII C - "Use - by date or recommended last consumption date or expiry date" means the date which signifies the end of the estimated period under any stated storage conditions, after which product probably will not have the quality attributes normally expected by the consumers and the food shall not be marketable."

4. In rule 36, of the said rules, -

(a) for the sub-rule (1), the following sub-rule shall be substituted, namely:-

“(1) The information required under these rules shall be given on the principal display panel of the package or container and such information may interalia include:

- (i) all the information be grouped together and given at one place; or
- (ii) the pre-printed information be grouped together and given in one place; and
- (iii) online information be grouped together in other place."

Explanation:- For the purpose of this rule, the "principal display panel" means that part of the container/ package which is intended or likely to be displayed or presented or shown or examined by the customer under normal and customary conditions of display, sale or purchase of the commodity contained therein."

(b) sub-rule(3) shall be omitted.

5. for sub-rule (2) of rule 37 A of the said rules, the following sub-rule shall be substituted, namely:-

“(2) In addition to the provisions including labeling requirements specified under these rules, the proprietary foods shall also conform to the following requirements, namely:-

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THE GAZETTE OF INDIA : EXTRAORDINARY

[Part II—Sec. 3(i)]

- (a) the name of the food and category under which it falls in these rules shall be mentioned on the label;
- (b) the proprietary food product shall comply with all other regulatory provisions specified in these rules and in Appendix - C."
6. for sub-rule (2) of rule 40 of the said rules, the following sub-rule shall be substituted, namely:-
- "(2) (i) Any fruit syrup, fruit juice, fruit squash, fruit beverages, cordial, crush or any other fruit products standardized under Appendix B of these rules, which does not contain the specified amount of fruit juice or fruit pulp or fruit content shall not be described as fruit syrup, fruit juice, fruit squash, fruit beverages, cordial, crush or any other fruit product as the case may be;
- (ii) Any food product which does not contain specified amount of any fruit and is likely to deceive or mislead or give a false impression to the consumer that the product contains fruit whether by use of words or pictorial representation shall be clearly and conspicuously marked on the label as '(NAME OF THE FRUIT) FLAVOURED';
- (iii) any food product, which contains only fruit flavours whether natural flavours and natural flavouring substances or nature identical flavouring substances or artificial flavouring substances as single or in combination, shall not be described as a fruit product and the word 'ADDED (NAME OF FRUIT) FLAVOURED' shall be used in describing such a product;
- (iv) carbonated water containing no fruit juice or fruit pulp shall not have a label which may lead the consumer into believing that it is a fruit product."
7. In rule 42 of the said rules, in sub-rule (ZZZ), the clause (24) shall be omitted.
8. In rule 64 BB of the said rules, for the existing statement and the Note, regarding added flavour, the following statement and Notes shall be substituted, namely:-

CONTAINS ADDED FLAVOUR (specify type of flavouring agent as per rule 63)

Note:- In addition to above statement, the common name or class name of the flavour as specified in rule 32(b) shall also be mentioned on label and if such a statement is displayed, the flavour used in the products need not be mentioned in the list of ingredients."

[F. No. P. 15014/9/2001-PH (Food) Vol. II]

DEBASISH PANDA, Jt. Secy.

Note :- The principal rules were published in the Gazette of India vide notification number S.R.O. 2106, dated the 12th September, 1955 and were lastly amended vide notification number G.S.R. 206(E), dated the 25.03.2008.